

THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION  
No. 5:19-cv-145-D

ISLET SCIENCES, INC.,	)	
	)	
Plaintiff	)	
	)	
v.	)	
	)	
AVOLYNT, INC., BRIGHTHAVEN	)	
VENTURES, LLC, WILLIAM WILKISON,	)	
and JAMES GREEN,	)	
	)	
Defendants	)	
and	)	<b>CASE NO.5:19-cv-145-D</b>
	)	
AVOLYNT, INC., BRIGHTHAVEN	)	
VENTURES, LLC, WILLIAM	)	
WILKISON, and JAMES GREEN,	)	
	)	
Counterclaim Plaintiffs,	)	
	)	
v.	)	
	)	
ISLET SCIENCES, INC., JOHN F. STEEL,	)	
IV., LARRY K. ELLINGSON,	)	
JAMES A. HARPER, RICHARD D.	)	
PILNIK, EUGENE M. MANNHEIMER,	)	
and GARY R. KEELING,	)	
	)	
Counterclaim-Defendants.	)	

**PROTECTIVE ORDER**  
**(AS MODIFIED)\***

**1. PURPOSE**

Disclosure and discovery activity in this Action are likely to involve production of confidential, proprietary, or private information for which special protection from public

\* See paragraph 8.

disclosure and from use for any purpose other than prosecuting this Action may be warranted. Accordingly, the Court hereby issues the following Protective Order. This Order does not confer blanket protections on all disclosures or responses to discovery. Rather, the protection it affords from public disclosure and unauthorized use extends only to the limited information or items that are entitled to confidential treatment according to the terms of this Order. The parties to this Action may modify or replace this order according to the provisions of Section 10 below.

## **2. DEFINITIONS**

**2.1.** The “**Action**” shall refer only to the above-captioned case(s) and shall not include related cases unless this Protective Order is amended to explicitly cover such related cases.

**2.2.** The “**Agreement**” shall refer to the Agreement to Be Bound attached hereto as Exhibit A. All executed Agreements to this Protective Order are Confidential Information pursuant to this Protective Order.

**2.3.** “**Confidential Information**” shall mean information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26. Confidential Information not designated under a more restrictive designation shall be marked or otherwise designated “CONFIDENTIAL.”

**2.4.** “**Designated In-House Counsel**” shall mean In-House Counsel who seek access to “Highly Confidential Information” in this Action.

**2.5.** “**Disclosure or Discovery Material**” shall mean all items or information, regardless of the medium or manner in which it is generated, stored, or maintained (including, among other things, testimony, transcripts, and tangible things), that are produced or generated in disclosures or responses to discovery in this matter.

**2.6.** “**Expert**” shall mean a person with specialized knowledge or experience in a matter pertinent to the litigation who (1) has been retained by a Party or its counsel to serve as an

expert witness or as a consultant in this Action, (2) is not a current employee of a Party for purposes other than this Action, and (3) at the time of retention, is not anticipated to become an employee of a Party.

**2.7. “Final Disposition”** shall mean that (1) final judgment has been entered and any appeals of the final judgment have concluded, or (2) all claims of any kind asserted in the Action have been dismissed with prejudice by the Party or Parties who brought such claims.

**2.8. “Highly Confidential Information”** shall mean extremely sensitive “Confidential Information,” the disclosure of which to another Party or Non-Party would create a substantial risk of serious harm that could not be avoided by less restrictive means. Highly Confidential Information not designated with a more restrictive designation, to the extent possible, shall be marked or otherwise designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY.”

**2.9. “In-House Counsel”** shall mean attorneys who are employees of a Party or Non-Party. In-House Counsel does not include Outside Counsel.

**2.10. “Non-Party”** shall mean any natural person, partnership, corporation, association, or other legal entity not named as a Party to this Action

**2.11. “Outside Counsel”** attorneys who are not employees of a Party to this Action but are retained to represent or advise a Party to this Action and have appeared in this Action on behalf of that Party or are affiliated with a law firm which has appeared on behalf of that Party.

**2.12. “Party”** shall mean any party to this Action, including all of its officers, directors, employees, consultants, Experts, and Outside Counsel (and their support staffs).

**2.13. “Producing Party”** shall mean a Party or Non-Party that produces Disclosure or Discovery Material in this Action. Any Producing Party may designate information or items under the provisions of this Protective Order.

**2.14. “Professional Vendors”** shall mean persons or entities that provide litigation support services (e.g., photocopying; videotaping; translating; preparing exhibits or demonstrations; and organizing, storing, or retrieving data in any form or medium) and their employees and subcontractors.

**2.15. “Protected Material”** shall mean any Disclosure or Discovery Material that is designated under this Protective Order.

**2.16. “Receiving Party”** shall mean a Party or Non-Party that receives Disclosure or Discovery Material in this Action.

### **3. DESIGNATING CONFIDENTIAL INFORMATION**

**3.1. Manner and Timing of Designations.** Designation under this Order requires the Producing Party to affix the applicable legend (“CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY”) to each page or item that contains or embodies protected material. For testimony given in a deposition or other proceeding, the Producing Party shall specify all protected testimony and the level of protection being asserted. It may make that designation during the deposition or proceeding, or may invoke, on the record or by written notice to all parties within three business days, a right to have up to 21 days from the deposition or proceeding to make its designation.

3.1.1. A Party or Non-Party that makes original documents or materials available for inspection need not designate them for protection until after the inspecting party has identified which material it would like copied and produced. During the inspection and before the designation, all material shall be treated as “HIGHLY CONFIDENTIAL –

OUTSIDE COUNSEL ONLY.” After the inspecting party has identified the documents it wants copied and produced, the producing party must designate the documents, or portions thereof, that qualify for protection under this Order.

3.1.2. Parties shall give advance notice if they expect a deposition or other proceeding to include designated material so that the other parties can ensure that only authorized individuals are present at those proceedings when such material is disclosed or used. The use of a document or thing as an exhibit at a deposition shall not in any way affect its designation. Transcripts containing designated material shall have a legend on the title page noting the presence of designated material, and the title page shall be followed by a list of all pages (including line numbers as appropriate) that have been designated, and the level of protection being asserted. The Producing Party shall inform the court reporter of these requirements. Any transcript that is prepared before the expiration of the 21-day period for designation shall be treated during that period as if it had been designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” unless otherwise agreed. After the expiration of the 21-day period, the transcript shall be treated only as actually designated.

**3.2. Inadvertent Failure to Designate.** An inadvertent failure to designate or an inadvertent mis-designation of confidential information or items does not, standing alone, waive the Producing Party’s right to secure protection under this Order for such material. Upon discovery of the inadvertently undesignated or mis-designated confidential information or items, the Producing Party must promptly notify the Receiving Party of the error, including (1) an identification of each item or piece of information that was undesignated or mis-designated, and (2) the proper designation for each such item or piece of information. The Producing Party shall

further, if applicable, produce a properly designated replacement for each such item. Upon prompt notification by the Producing Party, the Receiving Party must make reasonable efforts to assure that the material is treated in accordance with the provisions of this Order, and within a reasonable time following receipt of any replacement items with a corrected designation, return or destroy the undesignated or mis-designated item(s). The provisions of this section do not apply to inadvertently disclosed attorney-client privileged communications or protected attorney work product materials. Any inadvertently disclosed attorney-client privileged communications or protected attorney work product material shall be handled pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

**3.3. Over-Designation Prohibited.** Any Party or Non-Party who designates information or items for protection under this Order as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY,” shall use best efforts to only designate the specific material that qualifies under the appropriate standards. To the extent practicable, only those parts of documents, items, or oral or written communications that require protection shall be designated. Designations with a higher confidentiality level when a lower level would suffice are prohibited. Designation under this Order is allowed only if the designation is necessary to protect material that, if disclosed to persons not authorized to view it, would cause competitive or other recognized harm. If a Producing Party learns that information or items that it designated for protection do not qualify for protection at all or do not qualify for the level of protection initially asserted, that Producing Party must promptly notify all Parties that it is withdrawing the mistaken designation and, if applicable, re-produce the item with the appropriate designation, if any.

#### **4. CHALLENGING DESIGNATIONS OF CONFIDENTIAL INFORMATION**

**4.1. Timing of Challenges.** Any Party or Non-Party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Producing Party's confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a significant disruption or delay of the litigation, the right to challenge a confidentiality designation is not waived by electing not to mount a challenge promptly after the original designation is disclosed.

**4.2. Meet and Confer.** The parties shall attempt to resolve each challenge to a confidentiality designation in good faith by meeting and conferring about each challenged designation prior to seeking judicial intervention. To initiate the meet and confer process under this section, the challenging party shall provide written notice that identifies the designated material, the then-current designation of each challenged item, and the proposed new designation (if any) for each challenged item.

**4.3. Judicial Intervention.** A challenging party may only seek judicial intervention if the parties involved in the dispute cannot resolve the dispute through the meet and confer process.

4.3.1. To initiate judicial intervention, the challenging party shall provide written notice to the Producing Party stating (1) that it believes the meet and confer process under section 4.2 has failed to resolve the challenge, and (2) identifying the designated material for which the challenge has not been resolved.

4.3.2. Within 14 calendar days of receipt of such written notice, the Producing Party shall file a motion with the Court under the Court's Local Civil Rules establishing the basis for each remaining challenged designation. Such motion shall be a "Discovery

Motion” under the local rules. The Producing Party shall bear the burden of establishing that each remaining challenged designation is proper.

4.3.3. Failure by the Producing Party to timely file a motion pursuant to section 4.3.2 shall be deemed an agreement by the Producing Party that the remaining challenged materials were improperly designated, and the remaining challenged materials shall be immediately treated as re-designated as proposed by the challenging party.

4.3.4. Following a successful challenge, or in the event the Producing Party fails to timely file a motion pursuant to section 4.3.2, and unless otherwise ordered by the Court, the Producing Party shall reproduce or re-designate, as appropriate, the remaining challenged designated material accordingly within 14 days or as otherwise agreed by the challenging and designating parties.

## **5. ACCESS TO AND USE OF PROTECTED MATERIAL**

**5.1. Basic Principles.** A Receiving Party may use Protected Material only for this Action. Protected Materials may be disclosed only to the categories of persons and under the conditions described in this Order.

**5.2. Access to Protected Material Designated “CONFIDENTIAL.”** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may disclose any material designated CONFIDENTIAL only to:

- (a) The Receiving Party’s Outside Counsel in this action and employees of Outside Counsel to whom disclosure is reasonably necessary;
- (b) The officers, directors, and employees of the Receiving Party to whom disclosure is reasonably necessary, and who have signed the Agreement;
- (c) Experts retained by the Receiving Party’s Outside Counsel to whom disclosure is reasonably necessary, and who have signed the Agreement;



- (d) The Court and its personnel;
- (e) Outside court reporters and their staff, professional jury or trial consultants, and professional vendors to whom disclosure is reasonably necessary, and who have signed the Agreement;
- (f) During their depositions, witnesses in the action to whom disclosure is reasonably necessary and who have signed the Agreement; and
- (g) The author or recipient of a document containing the material, or a custodian or other person who otherwise possessed or knew the information.

**5.3. Access to Protected Material Designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY.”** Unless permitted in writing by the Producing Party, a Receiving Party may disclose material designated HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY without further approval only to:

- (a) The Receiving Party’s Outside Counsel in this Action and employees of Outside Counsel to whom it is reasonably necessary to disclose the information;
- (b) The Court and its personnel;
- (c) Outside court reporters and their staff, professional jury or trial consultants, and professional vendors to whom disclosure is reasonably necessary, and who have signed the Agreement; and
- (d) The author or recipient of a document containing the material, or a custodian or other person who otherwise possessed or knew the information.

**5.4. Procedures for Approving or Objecting to Disclosure of Protected Material Designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” to In-House Counsel or Experts.** Unless agreed to in writing by the Producing Party:

(a) A party seeking to disclose to In-House Counsel any material designated **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY** must first make a written request to the Producing Party providing the full name of the specific in-house counsel, the city and state of such counsel's residence, and such counsel's current and reasonably foreseeable future primary job duties and responsibilities in sufficient detail to determine present or potential involvement in any competitive decision-making.

(b) A party seeking to disclose to an Expert any information or item that has been designated **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY** must first make a written request to the Producing Party that (1) identifies the general categories of **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY** information that the Receiving Party seeks permission to disclose to the Expert, (2) sets forth the full name of the Expert and the city and state of his or her primary residence, (3) attaches a copy of the Expert's current resume or curriculum vitae, (4) identifies the Expert's current employer(s), and (5) identifies each person or entity from whom the Expert has received compensation or funding for work in his or her areas of expertise (including in connection with litigation) in the past four years. If the Expert believes any of this information at (4) - (5) is subject to a confidentiality obligation to a third party, then the Expert should provide whatever information the Expert believes can be disclosed without violating any confidentiality agreements, and the party seeking to disclose the information to the Expert shall be available to meet and confer with the Producing Party regarding any such confidentiality obligations.

(c) A party that makes a request and provides the information specified in paragraphs 5.4(a) or 5.4(b) may disclose the designated material to the identified In-House

Counsel or Expert unless, within seven business days of delivering the request, the party receives a written objection from the Producing Party providing detailed grounds for the objection.

(d) Should the Producing Party object to the identified In-House Counsel or Expert, the party that made the request may challenge the objection by meeting and conferring with the Producing Party in good faith to resolve the objection. Should the parties be unable to resolve the objection through the meet and confer process, the party that made the request may seek judicial intervention by filing a motion under the Court's Local Civil Rules.

## **6. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL**

If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Protected Material to any person or in any circumstance not authorized under this Protective Order, the Receiving Party must immediately (a) notify in writing the Producing Party of the unauthorized disclosures, (b) use its best efforts to retrieve all unauthorized copies of the Protected Material, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons to execute the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit A.

## **7. FILING PROTECTED MATERIAL**

In accordance with § V.G(1)(e) of the Court's Electronic Case Filing Administrative Policies and Procedures Manual ("Policy Manual"), in the event that a filing Party seeks to file materials that have been designated "CONFIDENTIAL," "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY," by another Party, individual or non-party, the filing Party shall provisionally file the materials under seal in accordance with Local Civil Rule 79.2, with notice served on the Party, individual or non-party who desires to maintain the materials under seal. In accordance § V.G(1)(e)(i), the filing Party will submit a notice of filing in lieu of a motion to seal and the filing of these third party material under seal, by itself, shall not be

binding on the Court. However, documents submitted under seal in accordance with § V.G(1)(e) will remain under seal pending the Court's ruling on the motion to seal. Within seven (7) days after such notice, the Party, individual or non-party shall file a motion to seal and supporting memorandum in accordance with § V.G(1) of the Policy Manual. Where a Party seeks to submit documents to the Court which have been designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY" by the submitting Party, the submitting Party may, in its discretion, bring a motion to file such documents under seal pursuant to Local Civil Rules 7.1, 79.2, and § V.G(1) of the Court's Policy Manual. Where a submitting Party intentionally declines to seek an order sealing documents submitted to the Court designated as containing its own Confidential Information, the submitted material will no longer qualify for protection and subsequent treatment as containing Confidential Information under this Stipulated Protective Order.

In accordance with the Section G of the Policy Manual, except for motions filed under seal in accordance with Section V.G(1)(f) of the Policy Manual, each time a Party seeks to file under seal, said Party shall accompany the request with a motion to seal. The motion to seal may be filed without a supporting memorandum only if the filing Party can cite a statute or rule (federal, local or standing order) that requires the filing to be sealed. Absent such authority, the filing Party must submit a supporting memorandum that specifies: (i) the exact document or item, or portions thereof, for which filing under seal is requested; (ii) how such request to seal overcomes the common law or the First Amendment presumption to access; (iii) the specific qualities of the material at issue which justify sealing such material, taking into account the balance of competing interest in access; (iv) the reasons why alternatives to sealing are inadequate; and (v) whether there is consent to the motion. In addition to the motion and

supporting memorandum of law, the filing Party must set out such findings in a proposed order to seal.

**8. INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE PROTECTED MATERIAL**

Unless otherwise ordered by the court, the inadvertent production of privileged or otherwise protected material shall be governed by the "Order Pursuant to Federal Rule of Evidence 502(d) Regarding Production of Documents," entered contemporaneously herewith.

**9. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION**

**9.1. Subpoenas and Court Orders.** This Order in no way excuses non-compliance with a lawful subpoena or court order. The purpose of the duties described in this section is to alert the interested parties to the existence of this Order and to give the Producing Party an opportunity to protect its confidentiality interests in the court where the subpoena or order issued.

**9.2. Notification Requirement.** If a Party is served with a subpoena or a court order issued in other litigation that compels disclosure of any Protected Material in this Action, that Party must:

(a) Promptly notify the Producing Party in writing. Such notification shall include a copy of the subpoena or court order; and

(b) Promptly notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Order. Such notification shall include a copy of this Order.

**9.3. Wait For Resolution of Protective Order.** If the Producing Party timely seeks a protective order, the party served with the subpoena or court order shall not produce any Protected Material in this Action before a determination by the court where the subpoena or order issued, unless the party has obtained the Producing Party's permission. The Producing Party shall bear the burden and expense of seeking protection of its confidential material in that court.

## **10. MODIFICATION OR REPLACEMENT OF THIS PROTECTIVE ORDER**

**10.1. General Principles.** A Party or Parties to this Action may request modification or replacement of this Protective Order by moving the Court.

**10.2. Manner of Making Amendments.** Any proposed amendments to the Protective Order must be presented to the Court by filing two copies of the entire Protective Order. The first copy shall include markings indicating the proposed amendments, and the second copy shall be a clean copy for entry by the Court.

**10.3. By Stipulation.** The Parties may submit stipulated amendments to this Protective Order, or a stipulated replacement protective order, for entry by the Court at any time.

**10.4. On Motion.** A Party or Parties may move the Court for entry of amendments to this Protective Order without the agreement of all Parties.

10.4.1. Prior to moving the Court, the requesting party or parties must meet and confer with the other parties regarding any proposed amendments. Only upon a failure to reach agreement regarding any proposed amendments may the requesting party or parties move the Court under the Court's Local Civil Rules for entry of the proposed amendments.

10.4.2. Should different Parties have competing proposed amendments to the same portion or portions of this Protective Order, or competing proposals for new

provisions to this Protective Order, rather than filing a motion under the Court's Local Civil Rules, the Parties shall file a joint motion indicating the competing proposed amendments and setting forth the reasons supporting each proposed amendment, and, if applicable, the opposing party's or parties' responses thereto. Such joint motion shall also include all other proposed amendments to this Protective Order, whether by one or both parties, whether opposed or agreed upon by the parties, and setting forth the parties' respective positions on such proposed amendments.

10.4.3. Within 7 calendar days of resolution of a motion under section 10.4, and if applicable, the moving Party or Parties, or if by joint motion under section 10.4.2, the Parties jointly, shall file the amended protective order according to section 10.2.

## **11. FINAL DISPOSITION**

Within 60 days after Final Disposition of this action, each Receiving Party shall return all designated material to the Producing Party or destroy such material, including all copies, abstracts, compilations, summaries, and any other format reproducing or capturing any designated material. If requested by the Producing Party, the Receiving Party must submit a written certification to the Producing Party by the 60 day deadline that (1) identifies (by category, where appropriate) all the designated material that was returned or destroyed, and (2) affirms that the receiving party has not retained any copies, abstracts, compilations, summaries, or any other format reproducing or capturing any of the designated material. This provision shall not prevent counsel from retaining an archival copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain designated material. Any such archival copies remain subject to this Order.

SO ORDERED this 23rd day of June, 2020.



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James E. Gates  
United States Magistrate Judge



**EXHIBIT A****ACKNOWLEDGEMENT AND AGREEMENT TO BE BOUND**

I, \_\_\_\_\_ [print or type full name],  
of \_\_\_\_\_  
[print or type full address], declare under penalty of perjury that I have read in its entirety and understand the Protective Order that was issued by the United States District Court for the Eastern District of North Carolina on \_\_\_\_\_ in the case of *Islet Sciences, Inc. v. Avolynt, Inc. et al.*, Case No. 5:19-cv-145-D.

I agree to comply with and to be bound by all the terms of this Protective Order and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Protective Order to any person or entity except in strict compliance with the provisions of this Order. I also agree to notify any stenographic or clerical personnel who are required to assist me of the terms of this Order.

I understand that I am to retain all copies of any Protected Material, however designated, in a secure manner, and that all copies are to remain in my personal custody until I have completed my assigned duties, whereupon the copies and any writings prepared by me containing any information designated as Protected Material are to be returned to counsel who provided me with such material or destroyed, with certification of destruction.

I further agree to submit to the jurisdiction of the United States District Court for the Eastern District of North Carolina for the purpose of enforcing the terms of this Protective Order, even if such enforcement proceedings occur after termination of this Action.

Date: \_\_\_\_\_

Printed name: \_\_\_\_\_

Signature: \_\_\_\_\_